



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/581,166

05/31/2006

Donald J. Marsh

21457P

3912

210 7590 12/09/2009
MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,166	Applicant(s) MARSH ET AL.	
	Examiner ROY TELLER	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment, received 9/22/09.

Claims 1-15 are under examination.

Response to Amendments/Arguments

Applicant's arguments and/or amendments filed 9/22/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (WO 03/006604) in view of Ploj et al. (Brain Research Bull., vol.59, No. 2, pp-97-104, 2002)

The instant claims are drawn to a method of inhibiting alcohol consumption comprising administering a therapeutically effective amount of a selective melanocortin 4 receptor agonist to a subject in need thereof wherein the selective melanocortin 4 receptor agonist is a compound of Formula I.

Art Unit: 1654

Bednarek discloses selective agonists of melanocortin 4 receptors of formula I that are useful in the treatment of disorders or diseases mediated through the MC-4 receptor. Selective melanocortin 4 receptor agonists are useful to inhibit alcohol consumption. Bednarek discloses the various compounds of formula I. See, for example, abstract, page 2, line 25- page 3, line 15, page 3, lines 17-21, claims 1-10. Bednarek does not disclose a method of inhibiting alcohol consumption comprising administering a therapeutically effective amount of a selective melanocortin 4 receptor agonist

Ploj discloses melanocortin (MC) peptides that could reduce excessive ethanol intake. Ploj discloses that the MC system and, in particular, the melanocortin MC4-receptor may be involved in drug dependence mechanisms and adaptive processes during addiction. See, for example, abstract, page 97 and page 102. Ploj does not disclose the various compounds of formula I.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the various compounds of formula I taught by Bednarek *et al.* and to link the resulting peptide to the disclosure that melanocortin (MC) peptides that could reduce excessive ethanol intake as taught by Ploj *et al.*

The skilled artisan would have been motivated to link selective agonists of melanocortin 4 receptors of formula I based on the teaching of Bednarek *et al.* because Bednarek discloses that selective agonists of melanocortin 4 receptors of formula I that are useful in the treatment of disorders or diseases mediated through the MC-4 receptor. There would have been a reasonable expectation of success given that Ploj *et al.* teach that melanocortin (MC) peptides that could reduce excessive ethanol intake.

Art Unit: 1654

Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
12/7/09

/Christopher R. Tate/
Primary Examiner, Art Unit 1655